

National Institute of Environmental Health Sciences (NIEHS)

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## Countries Unite to Reduce Animal Use in Product Toxicity Testing Worldwide U.S., Canada, Japan and European Union Sign International Agreement

Representatives from four international agencies, including the director of the U.S. National Toxicology Program (NTP), today signed a memorandum of cooperation that could reduce the number of animals required for consumer product safety testing worldwide. The agreement between the United States, Canada, Japan and the European Union will yield globally coordinated scientific recommendations on alternative toxicity testing methods that should speed their adoption in each of these countries, thus reducing the number of animals needed for product safety testing. The memorandum is available at <a href="http://iccvam.niehs.nih.gov/docs/about\_docs/ICATM-MOC.pdf">http://iccvam.niehs.nih.gov/docs/about\_docs/ICATM-MOC.pdf</a>.

"Signing this international agreement demonstrates our commitment to finding and advancing alternatives to animal testing," said Linda Birnbaum, Ph.D., director of the NTP and National Institute of Environmental Health Sciences, part of the National Institutes of Health. "This agreement will help us achieve greater efficiency by avoiding duplication of effort and allowing us to leverage limited resources."

Birnbaum signed as the U.S. representative on behalf of the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), one of the national validation organizations participating in the agreement. Others who signed include Elke Anklam, Ph.D., for the European Centre for the Validation of Alternative Methods (ECVAM), David Blakey, D.Phil., for the Environmental Health Science and Research Bureau within Health Canada, and Masahiro Nishijima, Ph.D. for the Japanese Centre for the Validation of Alternative Methods (JaCVAM).

The agreement promotes enhanced international cooperation and coordination on the scientific validation of non- and reduced-animal toxicity testing methods. If the toxicity testing methods are shown to be reproducible based on strong scientific information, and able to accurately identify product related health hazards, the tests are more readily accepted by regulatory agencies.

"The memorandum covers three critical areas of test method evaluation: validation studies, independent scientific peer review meetings and reports, and development of test

method recommendations for regulatory consideration," said Marilyn Wind, Ph.D., chair of the Interagency Coordinating Committee on the Validation of Alternative Methods and a scientist at the Consumer Product Safety Commission (CPSC).

"This international cooperation will benefit both people and animals," said William Stokes, D.V.M., director of NICEATM and executive director of ICCVAM. Stokes is also an assistant surgeon general in the U.S. Public Health Service. "The cooperation will serve an important role in translating research advances into more effective public health prevention tools. It will speed the adoption of new test methods based on advances in science and technology that will provide more accurate predictions of safety or hazard. Animal welfare will also be improved by the national and international acceptance of alternative test methods that reduce, refine, and replace the use of animals."

Federal agencies are committed to the welfare of animals used in research. All animals used in federally-funded research are protected by laws, regulations and policies to ensure they are used in the smallest number possible and with the greatest commitment to their comfort. ICCVAM is working to promote the development and validation of alternative test methods. Alternative test methods are those that accomplish one or more of the 3Rs - reducing the number of animals used in testing, or refining procedures so animals experience less pain and distress, or replacing animals with non-animal systems.

"We are very pleased to be part of this effort and to continue our already successful collaboration in a formalized manner," said Elke Anklam, Ph.D., director for the Institute of Health and Consumer Protection for the European Commission's Joint Research Centre, where the European Centre for the Validation of Alternative Methods, ICCVAM's European counterpart, is located. Anklam has signed the agreement as representative on behalf of the EU. Her colleague Joachim Kreysa, Ph.D., the recently appointed head of ECVAM, further remarked, "I am enthusiastic about the agreement. Our collaboration will help to identify and embrace scientifically sound and robust new testing approaches, ensuring that safety assessments are never compromised, while at the same time reduce the need for animal testing."

"Although we've had informal collaborations over the years, this more formal agreement will allow us to work more efficiently and effectively," said Hajime Kojima, Ph.D., director of the Japanese Centre for the Validation of Alternative Methods.

David Blakey, D.Phil., director of the Environmental Health Science and Research Bureau within Health Canada, added that the effort is a major step forward. "Increased coordination, collaboration and communication will clearly enhance the global progress in this important area."

The European Centre for the Validation of Alternative Methods coordinates validation studies on proposed alternative methods, evaluates the results by peer review, and provides recommendations to the European Union National Coordinators for regulatory acceptance of the methods validated. For more information on ECVAM, visit <a href="http://ecvam.jrc.it/">http://ecvam.jrc.it/</a>.

The Japanese Centre for the Validation of Alternative Methods is a component of Japan's National Institute of Health Sciences and was established in 2005 to coordinate validation studies on proposed alternative methods, conduct peer reviews of test methods, and provide recommendations to regulatory authorities.

The Environmental Health Science and Research Bureau within Health Canada coordinates activities relevant to health-related test method validation and acceptance issues. For additional information, visit <a href="http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/sep-psm/ehsrb-bsser-eng.php">http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hecs-dgsesc/sep-psm/ehsrb-bsser-eng.php</a>.

The National Toxicology Program (NTP) is an interagency program established in 1978. The program was created as a cooperative effort to coordinate toxicology testing programs within the federal government, strengthen the science base in toxicology, develop and validate improved testing methods, and provide information about potentially toxic chemicals to health, regulatory, and research agencies, scientific and medical communities, and the public. The NTP is headquartered at the National Institute of Environmental Health Sciences (NIEHS). For additional information, visit <a href="http://ntp.niehs.nih.gov">http://ntp.niehs.nih.gov</a>.

The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) administers and provides scientific support for ICCVAM and is a part of the NTP at the NIEHS. For additional information, visit NICEATM at <a href="http://iccvam.niehs.nih.gov/about/about\_NICEATM.htm">http://iccvam.niehs.nih.gov/about/about\_NICEATM.htm</a>.

NIEHS supports research to understand the effects of the environment on human health and is part of the National Institutes of Health (NIH). For more information on environmental health topics, visit our website at <a href="http://www.niehs.nih.gov">http://www.niehs.nih.gov</a>.

The National Institutes of Health — *The Nation's Medical Research Agency* — includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary federal agency for conducting and supporting basic, clinical and translational medical research, and it investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <a href="https://www.nih.gov">www.nih.gov</a>.

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